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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,944	03/12/2007	Chang Hahn	USAV2002-0244 US PCT	9525

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/595,944	HAHN ET AL.	
	Examiner	Art Unit	
	Q. JANICE LI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2-4,6,7 and 11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, drawn to claim 5 and linking claims 1-4, 8-10, is acknowledged. The applicant also elected a species defined by the combination of following elements: AP-1 as the candidate cis-acting regulatory element, luciferase as a specific reporter gene and immature dendritic cell as the host cell. Applicant indicated that element c) as listed in page 5 of the Restriction requirement is not deemed applicable. Hence, claims 1, 5, 8-10 read on the elected invention.

The traversal is on the ground(s) that these claims are so linked, search can be made without serious burden. This is not found persuasive because the mere existence of linking claim restriction indicates linking claims may impose a serious search burden in certain circumstances. In the instant case, it is maintained that each of the Inventions requires a separate search status and consideration. The inventions are mutually exclusive and independent methods for mapping numerous signal pathways via structural distinct cis-acting regulatory elements. Given the volume of today's literature and numbers of databases and given diverse search criteria, it would have place serious search burden on the Office if all of the claims are examined together. Additionally, the applicant fails to submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case, and thus these species are not obvious variants of each other based on the current record. The searches for groups II and I would have certain overlap, but they

are not co-extensive. M.P.E.P. states, "FOR PURPOSES OF THE INITIAL REQUIREMENT, A SERIOUS BURDEN ON THE EXAMINER MAY BE PRIMA FACIE SHOWN IF THE EXAMINER SHOWS BY APPROPRIATE EXPLANATION OF SEPARATE CLASSIFICATION, OR SEPARATE STATUS IN THE ART, OR A DIFFERENT FIELD OF SEARCH AS DEFINED IN MPEP § 808.02". Therefore, it is maintained that these inventions are distinct due to their divergent subject matter. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-14 are pending, however, claims 2-4, 6, 7, 11-14 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1, 5 and 8-10 are under current examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chanda et al.* (USP 7,344,833), in view of *Kikuchi et al.* (J Antimicrobial Chemother 2002;49:745-55) and *Kraal et al.* (J Exp Med 1986;163:981-97).

Chanda teaches methods for screening modulators of AP-1 transcription factor activities in a cell (e.g. the abstract). *Chanda* teaches AP-1 protein is normally expressed by lymphoid cells (immunocyte) and induces macrophage (immunocyte) phagocytosis and activation, and induces hematopoietic progenitor cell (immature dendritic cell) differentiation (e.g. column 1, lines 41-50). *Chanda* teaches when using cell-based assays, the steps for the screening include introducing into appropriate host cells vectors expressing a reporter gene and linked to the coding sequence of an AP-1 subunit under the control of an AP-1 transcription regulatory element (promoter and enhancer sequence); and activities of modulation are typically examined by measuring expression of the reporter genes (column 25, lines 41-59). In working examples, *Chanda* transfected HEK293 cells with a vector construct comprising a nucleic acid encoding AP-1 operably linked to luciferase reporter gene, applying a candidate modulator (stimulator) of AP-1, and measuring reporter gene activity in response to the modulator (e.g. figure 2). *Chanda* teaches the vector for delivering the nucleic acid may

be adenoviral vectors (column 34, lines 3-14). Although *Chanda* did not transfect an immunocyte in working examples, it was apparently known in the art that immunocytes are natural host cells for AP-1 as taught by *Chanda*.

Kikuchi supplemented *Chanda* by establishing the skilled in the art had reduced to use primary immunocyte for measuring AP-1 activity. *Kikuchi* teaches transfecting human peripheral blood monocytes with AP-1 reporter plasmid containing luciferase reporter gene operably linked to a promoter (see e.g. pages 746-7), administering clarithromycin or LPS stimulators, and measuring reporter gene activity to assess the effect of stimulators on IL-8 signal pathway and activation of AP-1 (e.g. figure 2).

Chanda in view of *Kikuchi* does not particularly teach immature dendritic cells. However, it was well known in the art that veil cells are immature dendritic cells. *Kraal* supplemented *Chanda* in view of *Kikuchi* by establishing methods of identifying iDC was well known in the art (e.g. the abstract and table I).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine whether a stimulus is capable of activating a AP-1 cis-acting regulatory element according to the knowledge as illustrated in *Chanda* in view of *Kikuchi* and *Kraal* to arrive at the claimed process and with a reasonable expectation of success. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7:30 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI/
Primary Examiner, Art Unit 1633

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
September 3, 2009